

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION**

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc. v. Activis Mid Atlantic LLC, et al.,
Civil Action No. 08-10852*

**MDL NO. 1456
Master File No. 01-12257-PBS
Subcategory Case No. 06-11337**

Hon. Patti B. Saris

**DEFENDANTS MYLAN INC., MYLAN PHARMACEUTICALS INC.,
AND UDL LABORATORIES, INC.'S AMENDED ANSWER
TO RELATOR'S AMENDED COMPLAINT**

Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and UDL Laboratories, Inc. (collectively, "Mylan"), through their undersigned counsel, hereby answer Relator Ven-A-Care of the Florida Keys, Inc.'s ("Relator") Amended Complaint Following Severance for Violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, dated May 21, 2008 (the "Complaint"), as follows:

1. Mylan denies the allegations contained in Paragraph 1 of the Complaint and in the unnumbered paragraphs preceding it.
2. Mylan denies the allegations contained in Paragraph 2 of the Complaint.
3. Mylan denies the allegations contained in Paragraph 3 of the Complaint.
4. Mylan denies the allegations contained in Paragraph 4 of the Complaint.
5. Mylan denies the allegations contained in Paragraph 5 of the Complaint.
6. Mylan denies the allegations contained in Paragraph 6 of the Complaint.
7. Mylan denies the allegations contained in Paragraph 7 of the Complaint

8. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and the footnote thereto and, therefore, denies those allegations.

9. Mylan denies the allegations contained in Paragraph 9 of the Complaint.

10. Mylan denies the allegations contained in Paragraph 10 of the Complaint.

11. Mylan denies the allegations contained in Paragraph 11 of the Complaint.

12. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and, therefore, denies those allegations.

13. Mylan denies the allegations contained in Paragraph 13 of the Complaint

14. Mylan denies the allegations contained in Paragraph 14 of the Complaint.

15. Mylan denies the allegations contained in Paragraph 15 of the Complaint.

16-17. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 16 and 17 of the Complaint and, therefore, denies those allegations.

18. Mylan denies the allegations in Paragraph 18 of the Complaint except admits that Mylan Pharmaceuticals Inc. is a corporation organized under the laws of West Virginia whose principal place of business is Morgantown, West Virginia and is a wholly-owned subsidiary of Mylan Inc., and that Mylan Inc. was formerly known as Mylan Laboratories, Inc. and is a corporation organized under the laws of Pennsylvania whose principal place of business is in Canonsburg, Pennsylvania.

19-22. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 19 through 22 of the Complaint and, therefore, denies those allegations.

23. Mylan denies the allegations in Paragraph 23 of the Complaint except admits that UDL Laboratories, Inc. is a corporation organized under the laws of Illinois whose principal place of business is Rockford, Illinois and is a wholly-owned subsidiary of Mylan Inc.

24. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 24 of the Complaint and, therefore, denies those allegations.

25. Mylan denies the allegations contained in Paragraph 25 of the Complaint and refers the Court to the statute cited therein for a complete statement of its content.

26. Mylan denies the allegations contained in Paragraph 26 of the Complaint and refers the Court to the statute and regulations cited therein for a complete statement of their content.

27. Mylan denies the allegations contained in Paragraph 27 of the Complaint and refers the Court to the statutes and legislation cited therein for a complete statement of their content.

28. Mylan denies the allegations contained in Paragraph 28 of the Complaint and refers the Court to the statute and regulation cited therein for a complete statement of their content.

29. Mylan admits the allegations contained in Paragraph 29 of the Complaint.

30. Mylan admits the allegations contained in Paragraph 30 of the Complaint.

31. Mylan denies the allegations contained in Paragraph 31 of the Complaint and refers the Court to the statute and regulation cited therein for a complete statement of their content.

32. Mylan denies the allegations contained in Paragraph 32 of the Complaint.

33. The allegations in Paragraph 33 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

34. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint and, therefore, denies those allegations.

35. The allegations contained in Paragraph 35 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

36. The allegations contained in Paragraph 36 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

37. The allegations contained in Paragraph 37 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

38. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 of the Complaint and, therefore, denies those allegations.

39. The allegations contained in Paragraph 39 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

40. Mylan denies the allegations contained in Paragraph 40 of the Complaint.

41. The allegations contained in Paragraph 41 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

42. Mylan denies the allegations contained in Paragraph 42 of the Complaint, except admits that it does not submit claims for reimbursement to federal health care programs.

43. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of the Complaint and, therefore, denies those allegations.

44. Mylan denies the allegations contained in Paragraph 44 of the Complaint.

45. Mylan denies the allegations contained in Paragraph 45 of the Complaint.

46. Mylan denies the allegations in Paragraph 46 of the Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. have provided some pricing information to price publishers.

47. Mylan denies the allegations contained in Paragraph 47 of the Complaint.

48. Mylan denies the allegations contained in Paragraph 48 of the Complaint.

49. Mylan denies the allegations contained in Paragraph 49 of the Complaint and refers the Court to the regulations cited therein for a complete statement of their content.

50. The allegations contained in Paragraph 50 state legal conclusions to which no response is required, and to the extent a response is required, Mylan denies the allegations.

51. Mylan denies the allegations contained in Paragraph 51 of the Complaint and the footnote thereto.

52. Mylan denies the allegations contained in Paragraph 52 of the Complaint.

53. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 53 of the Complaint and, therefore, denies those allegations.

54. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 of the Complaint and the footnote thereto and, therefore, denies those allegations.

55. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 55 of the Complaint and, therefore, denies those allegations.

56. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 56 of the Complaint and, therefore, denies those allegations.

57. Mylan denies the allegations in Paragraph 57 of the Complaint.

58. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 58 of the Complaint and, therefore, denies those allegations.

59. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 59 of the Complaint and, therefore, denies those allegations.

60-130. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 60 through 130 of the Complaint and, therefore, denies those allegations.

131. Mylan denies the allegations contained in Paragraph 131 of the Complaint.

132. Mylan denies the allegations contained in Paragraph 132 of the Complaint.

133. Mylan admits that Mylan Pharmaceuticals Inc. sells drugs. Mylan is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 133 of the Complaint and, therefore, denies those allegations.

134. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 134 of the Complaint and, therefore, denies those allegations.

135. Mylan denies the allegations contained in Paragraph 135 of the Complaint and refers the Court to the document referenced therein for a true statement of its content.

136. Mylan denies the allegations contained in Paragraph 136 of the Complaint.

137. Mylan denies the allegations contained in Paragraph 137 of the Complaint.

138. Mylan denies the allegations contained in Paragraph 138 of the Complaint.

139. Mylan denies the allegations contained in Paragraph 139 of the Complaint.

140. Mylan denies the allegations contained in Paragraph 140 of the Complaint.

141. Mylan denies the allegations contained in Paragraph 141 of the Complaint.

142. Mylan denies the allegations contained in Paragraph 142 of the Complaint.

143. Mylan denies the allegations contained in Paragraph 143 of the Complaint.

144. Mylan denies the allegations contained in Paragraph 144 of the Complaint.

145. Mylan denies the allegations contained in Paragraph 145 of the Complaint.

146. Mylan denies the allegations contained in Paragraph 146 of the Complaint.

147. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 147 of the Complaint and, therefore, denies those allegations.

148. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 148 of the Complaint and, therefore, denies those allegations.

149. Mylan admits that some of the drugs attributed to Mylan Pharmaceuticals Inc. in the Complaint are multiple-source drugs that are subject to Federal Upper Limits (“FULs”) and denies the remaining allegations contained in Paragraph 149 of the Complaint.

150. Mylan denies the allegations contained in Paragraph 150 of the Complaint.

151. Mylan denies the allegations contained in Paragraph 151 of the Complaint.

152. Mylan denies the allegations contained in Paragraph 152 of the Complaint.

153. Mylan denies the allegations contained in Paragraph 153 of the Complaint.

154-244. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraphs 154 through 244 of the Complaint and, therefore, denies those allegations.

245. Mylan denies the allegations contained in Paragraph 245 of the Complaint.

246. Mylan denies the allegations contained in Paragraph 246 of the Complaint.

247. Mylan admits that UDL Laboratories, Inc. sells drugs. Mylan is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 247 of the Complaint and, therefore, denies those allegations.

248. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 248 of the Complaint and, therefore, denies those allegations.

249. Mylan denies the allegations contained in Paragraph 249 of the Complaint.

250. Mylan denies the allegations contained in Paragraph 250 of the Complaint.

251. Mylan denies the allegations contained in Paragraph 251 of the Complaint.

252. Mylan denies the allegations contained in Paragraph 252 of the Complaint.

253. Mylan denies the allegations contained in Paragraph 253 of the Complaint.

254. Mylan denies the allegations contained in Paragraph 254 of the Complaint.

255. Mylan denies the allegations contained in Paragraph 255 of the Complaint.

256. Mylan denies the allegations contained in Paragraph 256 of the Complaint.

257. Mylan denies the allegations contained in Paragraph 257 of the Complaint.

258. Mylan denies the allegations contained in Paragraph 258 of the Complaint.

259. Mylan denies the allegations contained in Paragraph 259 of the Complaint.

260. Mylan denies the allegations contained in Paragraph 260 of the Complaint.

261. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 261 of the Complaint and, therefore, denies those allegations.

262. Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 262 of the Complaint and, therefore, denies those allegations.

263. Mylan admits that some of the drugs attributed to UDL Laboratories, Inc. in the Complaint are multiple-source drugs that are subject to FULs. Mylan is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 263 of the Complaint and, therefore, denies those allegations.

264. Mylan denies the allegations in Paragraph 264 of the Complaint.

265. Mylan denies the allegations in Paragraph 265 of the Complaint.

266. Mylan denies the allegations in Paragraph 266 of the Complaint.

267. Mylan denies the allegations in Paragraph 267 of the Complaint.

268-289. The allegations in Paragraphs 268 through 289 of the Complaint are directed to persons, entities or defendants other than Mylan, and Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations.

290. Answering Paragraph 290 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 289 of the Complaint.

291. Mylan denies the allegations contained in Paragraph 291 of the Complaint.

292. Mylan denies the allegations contained in Paragraph 292 of the Complaint.

293. Mylan denies the allegations contained in Paragraph 293 of the Complaint.

294. Answering Paragraph 294 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 293 of the Complaint.

295. Mylan denies the allegations contained in Paragraph 295 of the Complaint.

296. Mylan denies the allegations contained in Paragraph 296 of the Complaint.

297. Mylan denies the allegations contained in Paragraph 297 of the Complaint.

298. Answering Paragraph 298 of the Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 through 297 of the Complaint.

299. Mylan denies the allegations contained in Paragraph 299 of the Complaint.

300. Mylan denies the allegations contained in Paragraph 300 of the Complaint.

301. Mylan denies the allegations contained in Paragraph 301 of the Complaint.

302. Mylan denies the allegations contained in Paragraph 300 of the Complaint and the “WHEREFORE” Paragraphs.

DEFENSES

Without assuming the burden of proof of such defenses that it would not otherwise have, Mylan asserts the following defenses:

First Defense

The claims in the Complaint fail to state a claim against Mylan upon which relief can be granted.

Second Defense

Relator fails to plead its claims with the requisite particularity as required by Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

Third Defense

The United States has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Mylan as alleged in the Complaint.

Fourth Defense

Relator’s claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose, and Relator is not entitled to any tolling of any limitations period.

Fifth Defense

Relator’s claims are barred, in whole or in part, by the doctrines of *res judicata* and/or collateral estoppel.

Sixth Defense

Relator’s claims are barred because the United States has known throughout the relevant time period, from various public sources including its own investigations, that the

AWPs and WACs published in industry sources were not what Relator now claims them to have been.

Seventh Defense

Relator's claims are barred because the United States has known throughout the relevant time period that the reimbursement rates used by state Medicaid programs to reimburse providers were greater than the acquisition costs of the drugs and knowingly approved Medicaid reimbursement rates that resulted in payments that were higher than acquisition costs.

Eighth Defense

Relator's claims are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, *in pari delicto* and unclean hands.

Ninth Defense

Relator's claims are barred to the extent that the claims involve drugs reimbursed without reference to AWP or WAC.

Tenth Defense

Relator's claims are barred, in whole or in part, because Mylan's alleged statements, actions, or omissions were not the proximate cause of any alleged loss by the United States.

Eleventh Defense

The United States was negligent, careless, committed willful misconduct or was otherwise at fault in and about the matter referred to in the Complaint, and such conduct on the part of the United States caused and contributed to the injury complained of -- if any actually occurred.

Twelfth Defense

The Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration (“CMS”) directed, ordered, approved and/or ratified Mylan’s conduct, and Relator is, therefore, barred from asserting any claims based thereon.

Thirteenth Defense

Any and all actions taken by Mylan with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Fourteenth Defense

Relator’s claims against Mylan are barred because Mylan has complied with all applicable regulations of the federal government and the various state governments.

Fifteenth Defense

Relator’s claims are barred, in whole or in part, because any injuries sustained by the United States, if any, were the result of its own conduct or the intervening or superseding acts or omissions of third parties.

Sixteenth Defense

Relator’s claims against Mylan for damages are barred, in whole or in part, because the United States failed to mitigate and/or neglected to minimize its damages, and its failure to mitigate damages should proportionately reduce its recovery and the allocation of any fault, if any exists, attributable to Mylan.

Seventeenth Defense

Relator’s claims against Mylan for damages are barred, in whole or in part, because the United States would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Eighteenth Defense

Mylan is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered on behalf of the United States with respect to the same alleged injuries.

Nineteenth Defense

Relator's claims for damages against Mylan are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that the United States has received and paid for pharmaceuticals manufactured, marketed and sold by Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. after first learning of the information that forms the basis for the allegations in the Complaint.

Twentieth Defense

Any damages recovered by Relator must be limited by the applicable statutory ceilings on recoverable damages.

Twenty-First Defense

Relator fails to state a claim against Mylan sufficient to support an award for costs and/or attorneys' fees.

Twenty-Second Defense

Relator's claims are barred, in whole or in part, by the doctrines of mistake and mutual mistake.

Twenty-Third Defense

Relator's claims against Mylan are barred, in whole or in part, because the United States has failed to exhaust all available administrative remedies.

Twenty-Fourth Defense

Relator's claims are barred, in whole or in part, because they violate Mylan's rights under the Due Process and Ex Post Facto clauses of the United States Constitution insofar as Relator seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Twenty-Fifth Defense

The civil penalties sought against Mylan cannot be sustained because an award of the civil penalties sought by Relator would violate the United States Constitution, the Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII, the Due Process Clauses of the Fifth and Fourteenth Amendments, U.S. Const. amend. V and XIV.

Twenty-Sixth Defense

The granting of the relief prayed for in the Complaint is unconstitutional in that it would violate Mylan's right of commercial speech under the United States Constitution.

Twenty-Seventh Defense

Relator has failed to join one or more necessary parties, including the providers who allegedly received "windfall profits" from state Medicaid programs and the "compendia," including First DataBank, the Red Book, and Medi-Span that allegedly published "false" prices.

Twenty-Eighth Defense

Any or all causes of action in the Complaint are barred because of the lack of privity between the United States and Mylan.

Twenty-Ninth Defense

Any or all causes of action in the Complaint are barred because the statutes upon which Relator relies are vague and ambiguous.

Thirtieth Defense

Relator's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Thirty-First Defense

Relator's claims are barred because Mylan did not owe any duty to the United States and/or did not breach any duty owed to the United States.

Thirty-Second Defense

Relator's claims are barred, in whole or in part, by the government contractor and similar defenses because the various reimbursement systems employed by the state Medicaid programs, were designed and approved by the states, along with the federal government, to serve their policy purposes.

Thirty-Third Defense

Relator's claims for damages are barred, in whole or in part, because the United States' alleged damages, if any, are speculative and because of the impossibility of the ascertainment and allocation of these alleged damages.

Thirty-Fourth Defense

Relator's claims are barred, in whole or in part, by the filed rate doctrine.

Thirty-Fifth Defense

Relator has no standing or capacity to bring some or all of the claims raised in this suit, or to recover for any state's share of any Medicaid payment.

Thirty-Sixth Defense

To the extent punitive damages and/or penalty assessments are sought, Relator's punitive damages and/or penalty assessments claims against Mylan: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to

support a claim for punitive damages and/or penalty assessments against Mylan; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages and/or penalty assessments fail to give Mylan prior notice of the conduct for which punitive damages and/or penalty assessments may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Mylan's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States; (4) cannot be sustained because any award of punitive damages and/or penalty assessments exceeding the limits authorized by law would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution and common law; (5) cannot be sustained because an award of punitive damages and/or penalty assessments in this case, combined with any prior, contemporaneous, or subsequent judgments against Mylan for punitive damages and/or penalty assessments arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Mylan's products would constitute impermissible multiple punishments for the same wrong, in violation of Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution; and (6) cannot be sustained because any award of punitive damages and/or penalty assessments, which are penal in nature, without according Mylan the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Mylan's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution.

Thirty-Seventh Defense

The United States has suffered no damages because, pursuant to federal and state statutes, regulations and rules, state Medicaid programs were prohibited from reimbursing the provider at an amount greater than the provider's usual and customary charge. The provider's usual and customary charge is an amount set by the provider which it charges to certain non-Medicaid customers for the service of acquiring and dispensing the drug. The usual and customary charge was, therefore, a price reflecting the value of the provider's services, and, pursuant to federal and state statutes, regulations and rules, state Medicaid programs are not permitted to reimburse at an amount higher than this price. To the extent it is determined that the United States made any "overpayments," if any, they were due to the provider's failure to submit an accurate usual and customary charge or state Medicaid program's failure to comply with state and federal statutes, rules and regulations.

Thirty-Eighth Defense

Relator's claims are barred because throughout the relevant time period, CMS, the federal agency in charge of the Medicaid program, approved the various Medicaid programs' reimbursement rates while knowing that AWP and WAC were not fully discounted prices and/or the actual acquisition costs of providers.

Thirty-Ninth Defense

Mylan Inc. does not itself manufacture, market or sell drugs. Mylan Inc., Mylan Pharmaceuticals Inc., and UDL Laboratories, Inc. are separate and distinct corporate entities, each of which observe corporate formalities.

Fortieth Defense

Some or all of Relator's claims against Mylan arise from the United States' and the various states' failure to follow federal and state statutory and regulatory obligations in establishing reimbursement rates.

Forty-First Defense

Relator's claims are barred, in whole or in part, because any and all of Mylan's actions alleged by Relator were lawful, justified, pro-competitive, carried out in furtherance of Mylan's legitimate business interests, and constitute bona fide business competition.

Forty-Second Defense

Relator's claims are barred, in whole or in part, by the First Amendment of the United States Constitution.

Forty-Third Defense

Relator's claims against Mylan are misjoined with Relator's claims against other defendants and must be severed.

Forty-Fourth Defense

Relator's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct occurring in judicial, legislative or administrative proceedings of any kind or at any level of government.

Forty-Fifth Defense

State Medicaid programs knowingly use AWP and WAC in order to provide a margin that encourages providers to participate and to compensate for inadequate dispensing

fees. The United States is not entitled to any recovery of the so-called “spread,” and any recovery is entirely set off by those amounts attributable to the deficient dispensing fee.

Forty-Sixth Defense

Relator’s claims against Mylan are barred in whole or in part by the existence and terms of the written rebate agreement between Mylan and the Secretary of the Department of Health and Human Services (“HHS”), on behalf of HHS and certain states, entitled, “Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement,” which was entered into pursuant to 42 U.S.C. § 1396r-8 and requires Mylan to report to the federal government the average manufacturer prices for its drugs and to remit rebate payments to states based on those average manufacturer unit prices.

Forty-Seventh Defense

Relator’s claims are barred, in whole or in part, by the doctrines of consent and/or ratification because CMS approved of and ratified the prescription drug reimbursement methodology utilized by the state Medicaid programs.

Forty-Eighth Defense

Relator’s claims are barred, in whole or in part, by the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Forty-Ninth Defense

Relator’s claims are barred, in whole or in part, by the economic loss doctrine.

Fiftieth Defense

To the extent the United States or any other person or entity obtained or obtains recovery in any other action or proceeding predicated on the same factual allegations, it is barred

from seeking recovery against Mylan, in whole or in part, based on the doctrines of *res judicata* and collateral estoppel and the prohibition on double recovery for the same injury, including but not limited to any recovery obtained in any action brought by or on behalf of any state, or political subdivision thereof, which seeks recovery from Mylan of the same alleged Medicaid overpayments as the Complaint seeks in this action.

Fifty-First Defense

To the extent Mylan prevails in any other action or proceeding predicated on the same factual allegations, on any claim or issue – including but not limited to any action brought by or on behalf of any state, or political subdivision thereof, which seeks recovery from Mylan of the same alleged Medicaid overpayments as the Complaint seeks in this action – Relator’s claims are barred, in whole or in part, pursuant to the doctrines of *res judicata* and/or collateral estoppel.

Fifty-Second Defense

Relator’s claims are barred, in whole or in part, by the United States’ settlement agreement in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Third Defense

Relator’s claims are barred, in whole or in part, by the United States’ release of claims in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Fourth Defense

Relator's claims are barred, in whole or in part, by an accord and satisfaction between Mylan and the United States in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Sixth Defense

Relator's claims are barred, in whole or in part, by the payment made to the United States in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Seventh Defense

Relator's claims are barred, in whole or in part, by Relator's waiver of claims in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Eighth Defense

Relator's claims are barred, in whole or in part, by the doctrines of *res judicata* and/or collateral estoppel in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

Fifty-Ninth Defense

Mylan is entitled to a set-off for the amounts paid in connection with the action entitled *In re Lorazepam & Clorazepate Antitrust Litig.*, MDL No. 1290 (TFH), Misc. No.

99ms276 (TFH) (D.D.C.) against any amount recovered by Relator with respect to the same alleged injuries.

Sixtieth Defense

Relator's claims are barred, in whole or in part, by the voluntary payment doctrine.

Sixty-First Defense

Relator's claims are barred, in whole or in part, by the October 16, 2009 decision of the Supreme Court of Alabama in the case of *AstraZeneca L.P. et al. v. State of Alabama*, 1071439.

Sixty-Second Defense

Relator's claims are barred because the United States knew or should have known before the filing of the Complaint that published AWP's and WAC's do not represent actual averages of the prices at which providers or pharmacies are able to purchase pharmaceuticals, and are not net prices that reflect discounts.

Sixty-Third Defense

Relator's claims under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, are barred, in whole or in part, because the United States' remedy is limited by federal law to recovery on a contract-based theory under the Rebate Agreement.

Sixty-Fourth Defense

Relator's claims are barred because CMS's decision not to provide manufacturers' AMP's to State Medicaid Programs was arbitrary and capricious, an abuse of discretion, and not in accordance with law, and is contrary to the Medicaid Rebate Act, 42 U.S.C. § 1396r-8. As a result of CMS's approval of State Medicaid plans that reimbursed based

on AWP or WAC while in possession of AMPs, and its failure to provide AMP to the State Medicaid Programs, the United States cannot recover any damages based on allegations that Mylan's AWP and WAC were higher than the net AMP that Mylan provided.

Sixty-Fifth Defense

Relator is precluded from any recovery in this action because Relator and its affiliate, the Cobo Pharmacy, knowingly submitted reimbursement claims to the Florida Medicaid program with usual and customary charges that did not comply with federal and state requirements.

Sixty-Sixth Defense

Mylan hereby adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Mylan hereby reserves the right to amend its answer to assert other defenses and to supplement those asserted herein.

JURY DEMAND

Mylan denies that the Commonwealth has asserted any viable claims that would necessitate a trial by jury. To the extent the Court finds any claims triable, Mylan demands a trial by jury on all such claims.

Dated: December 3, 2009

Respectfully submitted,

KELLEY DRYE & WARREN LLP

/s/Christopher C. Palermo
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CERTIFICATE OF SERVICE

I, Christopher C. Palermo, hereby certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on December 3, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Christopher C. Palermo

Christopher C. Palermo